

be partially attributable to the inclusion of patients with adenocarcinoma histology in the AC group, which is associated with worse prognosis. A multicentric prospective trial including solely AC histology is needed for better management of this entity.

8015

POSTER

# Phase I Clinical Trial of S-1, Cisplatin and Concurrent Radiotherapy for Primary Cervical Cancer

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**Background:** Cisplatin based chemotherapy plus concurrent radiotherapy is widely used as the standard therapy for women with cervical cancer. S-1 is an oral fluoropyrimidine. A phase II study of S-1 monotherapy for recurrent or metastatic cervical cancer have been shown to be active against cervical cancer. S-1 has been also revealed to act as a radiosensitizer in preclinical models. A phase II study was conducted for locally advanced non-small cell lung cancer, and high response rates and tolerability were shown. In this study, we evaluated the maximum-tolerated dose (MTD) according to escalating dosage of S-1 in combination with a fixed dose of cisplatin and concurrent radiotherapy to patients with cervical cancer.

**Materials and Methods:** Eligible patients were 20–74 years old, had FIGO stage Ib – IVa cervical cancer, a performance status of 0–2, and no prior therapy. Patients were treated with cisplatin (50 mg/m<sup>2</sup>) on day 1 and S-1 (twice daily) on day 1–14 repeated every 4 weeks for two cycles. The S-1 starting dose was 60 mg/m<sup>2</sup>/day (level 1), and the dose was escalated to 80 mg/m<sup>2</sup>/day (level 2) as the results of adverse events. Radiation therapy was consisted of both external radiation therapy and high-dose-rate intracavitary brachytherapy.

**Results:** Level 1 and 2 were studied with six patients enrolled, respectively. One patient in level 1 developed grade3 venous thrombosis. In level 2, two patients developed grade 3 hyponatremia (one patient also had grade 3 venous thrombosis), and one patient experienced febrile neutropenia remained for eleven days. The adverse events of those four patients were predetermined dose-limiting toxicities in this study. Level 1 was determined as the MTD and recommend dose (RD). Eleven patients were evaluable for response: eight complete responses and three partial responses were obtained. Ten of eleven patients remained disease-free following treatment.

**Conclusions:** The use of S-1 with concurrent cisplatin and radiotherapy has acceptable toxicity and could be an active treatment for cervical cancer. This study is the first report of S-1 based chemotherapy and concurrent whole pelvic radiation in the world. We have started phase II study at the RD to evaluate the efficacy of this regimen.

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POSTER

# Radiotherapy in Cervical Cancer With Positive Para-aortic Lymph Nodes

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**Background:** The survival outcome of patients with carcinoma of the cervix and positive para-aortic lymph nodes is poor. Retrospective studies of these patients have demonstrated a 5-year survival of about 30%. Treatment failures occur in the pelvis, the para-aortic region, and at distant metastatic sites. The purpose of this study was to evaluate the response to treatments, acute and late toxicity of treatments to cervical cancer patients with positive para-aortic lymph nodes in our department.

**Material and Methods:** Between 2003 and 2010, we selected patients diagnosed with cervical cancer and para-aortic disease extension treated with extended field radiotherapy (RT) in our department. Response to treatment was evaluated by imaging control and/or cervicovaginal cytology. Toxicities were evaluated accordingly *RTOG Toxicity Criteria*.

**Results:** Fifty-six patients were eligible, with clinical Stages between IB1 and IVA (FIGO). Median age was 50 years. Thirteen patients had biopsy-proven para-aortic lymph node, remaining patients had clinically imaging positive nodes. Most of the patients (92%) had squamous-cell carcinoma as histologic diagnosis. One (1.7%) patient had surgery before RT, twenty-one (38%) were treated with chemoradiation (cisplatin 40 mg/m<sup>2</sup> i.v. weekly in the first 6 weeks of RT). Twelve (21%) patients had external beam RT with low-dose-rate intracavitary brachytherapy. Ten (18%) patients received radiation treatment with intensity modulated radiotherapy (IMRT). All patients received a median dose of 45 Gy to the pelvis and para-aortic lymph nodes (1.8 Gy/Fr, at 15 or 18MV). We reported acute nausea and

vomiting toxicity of at least grade 2 in 35% of patients, and bowel toxicity of at least grade 3 in 30% of patients. Acute toxicity was less reported in patients treated with IMRT, with no grade 3 bowel toxicity. The median duration of follow-up was 13.8 months. Late toxicity of large bowel and rectum of at least grade3 was reported in eight patients, and ureters complication in 4 patients. Nineteen patients (34%) had distant failure (ten patients had supra-clavicular node metastasis) during follow-up, and ten (18%) of patients with local recurrence failure.

**Conclusions:** Local and distant recurrences remain a problem in patients with para-aortic positive lymph nodes. IMRT provided treatments with less toxicity to surrounding structures. Nevertheless, long term follow-up and studies involving more patients with IMRT are needed to evaluate its respective clinical outcomes.

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POSTER

# Distribution Patterns of Metastatic Pelvic Lymph Nodes Assessed by CT/MRI in Patients With Uterine Cervical Cancer

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**Background:** To investigate distribution patterns of metastatic lymph nodes on pretreatment CT/MRI images of patients with locally advanced cervical cancer.

**Materials and Methods:** We enrolled 114 patients with uterine cervical cancer who were diagnosed with pelvic node metastases by CT/MRI ( $\geq 10$  mm in shortest diameter). Pretreatment CT/MRI data were collected at 6 institutions. The FIGO stage was IB1 in 2 patients (2%), IB2 in 6 (5%), IIA in 3 (3%), IIB in 49 (43%), IIIB in 50 (44%), and IVA in 4 (4%) patients. The median cervical tumour diameter assessed by T2-weighted MRI was 55 mm (range, 10–87 mm). The anatomical distribution of the nodes was allocated on CT/MRI images by two radiation oncologists and one diagnostic radiologist.

**Results:** 272 enlarged nodes were assessed as significant and judged as metastatic. The incidence of metastatic nodes according to nodal region was 104/114 (91%) for the obturator (OB), 31/114 (27%) for the external iliac (EI), 16/114 (14%) for the internal iliac (II), 22/114 (19%) for the common iliac (CI), and 6/114 (5%) for the presacral (PS) region. The EI region was subdivided into four categories: lateral, intermediate, medial, and lower. The OB and II regions were subdivided into two categories: upper and lower. The incidence of metastatic nodes was extremely high in both the upper OB region and the medial EI region (111/114). In contrast, the incidence was low in the lateral EI, lower EI, lower OB, lower II and PS regions. All cases with metastatic nodes in the II, CI, PS, lateral EI, and lower OB regions had metastatic nodes in other pelvic nodal regions concomitantly. Lymph node metastases in these regions were significantly related to FIGO stage ( $p = 0.017$ ) and number of metastatic lymph nodes ( $p < 0.0001$ ). Metastases to these regions did not appear in cases with lower FIGO stage disease and a smaller number of metastatic lymph nodes.

**Conclusions:** We demonstrated distribution patterns of pelvic node metastases on pretreatment CT/MRI images of patients with locally advanced cervical cancer. Individualization of the pelvic node clinical target volume (CTV) based on such findings should be encouraged for external beam radiotherapy in patients with cervical cancer.

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POSTER

# Prospective Study on Comparison Between 3D CT Based Volumetric Planning With Conventional Planning Using Orthogonal X-rays, in HDR Brachytherapy for Carcinoma Cervix – Jaslok Hospital and Research Centre Experience

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**Background:** Brachytherapy is an integral part of radiotherapy treatment in cancer cervix. Conventional planning compared with the image guided 3D